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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,837	02/13/2007	Chikao Morimoto	2144.0150002/RWE/RAS	8525
26111	7590	10/04/2007		
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER CHONG, KIMBERLY	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 10/04/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/584,837	<b>Applicant(s)</b> MORIMOTO ET AL.	
	<b>Examiner</b> Kimberly Chong	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-12, drawn to a method for identifying a substance that down regulates an immune response in an animal comprising determining whether the substance inhibits the interaction between CD26 and caveolin-1 and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- II. Claims 2-12, drawn to a method for identifying a substance that down regulates an immune response in an animal comprising determining whether the substance inhibits the interaction between caveolin-1 and Tollip and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- III. Claims 2-12, drawn to a method for identifying a substance that down regulates an immune response in an animal comprising determining whether the substance inhibits the interaction between caveolin-1, Tollip and IRAK-1 and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- IV. Claims 2-12, drawn to a method for identifying a substance that down regulates an immune response in an animal comprising determining

whether the substance inhibits phosphorylation of caveolin-1 and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.

- V. Claims 2-12, drawn to a method for identifying a substance that down regulates an immune response in an animal comprising determining whether the substance inhibits the phosphorylation of IRAK-1 and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- VI. Claims 2-12, drawn to a method for identifying a substance that down regulates an immune response in an animal comprising determining whether the substance inhibits the activation of NF-kB and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- VII. Claims 2-12, drawn to a method for identifying a substance that down regulates an immune response in an animal comprising determining whether the substance inhibits the up-regulation of CD86 expression and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- VIII. Claims 14-19, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that inhibits the interaction between CD26 and caveolin-1 classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.

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- IX. Claims 14-19, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that inhibits the interaction between caveolin-1 and Tollip, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.
- X. Claims 14-19, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that inhibits the interaction between caveolin-1, Tollip and IRAK-1, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.
- XI. Claims 14-19, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that inhibits phosphorylation of caveolin-1, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.
- XII. Claims 14-19, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that inhibits the phosphorylation of IRAK-1, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.

- XIII. Claims 14-19, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that inhibits the activation of NF- $\kappa$ B, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.
- XIV. Claims 14-19, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that inhibits the up-regulation of CD86 expression, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.
- XV. Claims 21-25, drawn to a pharmaceutical composition comprising an immunoregulatory agent that inhibits the CD26 signaling pathway administering to an animal an immunoregulatory agent that inhibits the up-regulation of CD86 expression, classifiable in class 536, subclass 24.5. This group is subject to a further restriction of siRNA target genes and siRNA sequences.
- XVI. Claims 27-31, drawn to a method for identifying a substance that up regulates an immune response in an animal comprising determining whether the substance inhibits the interaction between CD26 and caveolin-1 and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.

- XVII. Claims 27-31, drawn to a method for identifying a substance that up regulates an immune response in an animal comprising determining whether the substance inhibits the interaction between caveolin-1 and Tollip and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- XVIII. Claims 27-31, drawn to a method for identifying a substance that up regulates an immune response in an animal comprising determining whether the substance inhibits the interaction between caveolin-1, Tollip and IRAK-1 and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- XIX. Claims 27-31, drawn to a method for identifying a substance up regulates an immune response in an animal comprising determining whether the substance inhibits phosphorylation of caveolin-1 and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- XX. Claims 27-31, drawn to a method for identifying a substance that up regulates an immune response in an animal comprising determining whether the substance inhibits the phosphorylation of IRAK-1 and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- XXI. Claims 27-31, drawn to a method for identifying a substance that up regulates an immune response in an animal comprising determining whether the substance inhibits the activation of NF-kB and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.

- XXII. Claims 27-31, drawn to a method for identifying a substance that up regulates an immune response in an animal comprising determining whether the substance inhibits the up-regulation of CD86 expression and drawn to a kit comprising said substance, classifiable in class 435, subclass 6.
- XXIII. Claims 33-34, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent enhances the interaction between CD26 and caveolin-1 classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.
- XXIV. Claims 33-34, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that enhances the interaction between caveolin-1 and Tollip, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.
- XXV. Claims 33-34, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that enhances the interaction between caveolin-1, Tollip and IRAK-1, classifiable in class



514, subclass 44. This group is subject to a further restriction of siRNA sequences.

XXVI. Claims 33-34, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that enhances phosphorylation of caveolin-1, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.

XXVII. Claims 33-34, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that enhances the phosphorylation of IRAK-1, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.

XXVIII. Claims 33-34, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that enhances the activation of NF-kB, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.

XXIV. Claims 33-34, drawn to a method for treating, ameliorating, or preventing a disorder related to an immune response in an animal comprising administering to an animal an immunoregulatory agent that enhances the up-regulation of CD86 expression, classifiable in class 514, subclass 44. This group is subject to a further restriction of siRNA sequences.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are directed to related methods of screening for substances that down-regulate an immune response in an animal. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods are distinct because each method claimed are not obvious variants and each method has a materially different mode of operation. For example, each method comprises determining whether the substance inhibits different factors and interactions between the factors in the CD26 pathway. Moreover, the methods are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-VII and groups VIII-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and modes of operation. For example, the methods of groups I-VII are drawn to methods of screening for putative substances that down-regulates an immune response in an

animal by inhibiting CD26 signaling which is different than a method of treatment for a disorder related to an immune response comprising administering a known substance that inhibits CD26 signaling. Moreover, the methods are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-VII and group XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case product can be used in a materially different process, such as a process of treating or ameliorating a disease comprising administering an inhibitor of the CD26 signaling pathway.

Inventions of groups I-VII and groups XVI-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and modes of operation. For example, the methods of groups I-VII are drawn to methods of screening for putative substances that down-regulates an immune response in an animal by inhibiting CD26 signaling which is different than methods of groups XVI-XVII, drawn to screening for putative substances that up-regulates an immune response in an

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animal by inhibiting CD26 signaling. Moreover, the methods are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-VII and groups XXIII-XXIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and modes of operation. For example, the methods of groups I-VII are drawn to methods of screening for putative substances that down-regulates an immune response in an animal by inhibiting CD26 signaling which is different than methods of groups XXIII-XXIV, drawn to methods of treating a disorder related to an immune response in an animal comprising administering a substance that enhances the CD26 signaling pathway. Moreover, the methods are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups VIII-XIV and group XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

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materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case product can be used in a materially different process, such as a process of screening for inhibitors of the CD26 signaling pathway.

Inventions of groups VIII-XIV and groups XVI-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and modes of operation. For example, the methods of groups VIII-XIV are drawn to methods of treatment for disorders related to the immune response comprising administering a substance that inhibits the CD26 signaling which is different than methods of groups XVI-XVII, drawn to screening for putative substances that up-regulates an immune response in an animal by inhibiting CD26 signaling. Moreover, the methods are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups VIII-XIV and groups XXIII-XXIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and modes of operation. For example, the methods of groups VIII-XIV are drawn to methods of

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treatment for disorders related to the immune response comprising administering a substance that inhibits the CD26 signaling which is different than methods of groups XXIII-XXIV, drawn to methods of treating a disorder related to an immune response in an animal comprising administering a substance that enhances the CD26 signaling pathway. Moreover, the methods are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group XV and groups XVI-XXII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the product is drawn to a pharmaceutical composition that inhibits the CD26 signaling pathway and cannot be used in methods of groups XVI-XXII, which are drawn to screening for substances that up-regulate the CD26 signaling pathway.

Inventions of group XV and groups XVIII-XVIV are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the product is drawn to a pharmaceutical composition that inhibits the CD26 signaling pathway and cannot be used in methods of groups XVIII-XVIV, which are drawn to enhancing the CD26 signaling pathway.

Inventions of groups XVI-XXII and groups XXIII-XXIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs and modes of operation. For example, the methods of groups XVI-XXII are drawn to methods of screening for putative substances that up-regulate the CD26 signaling pathway which is different than methods of groups XXIII-XXIV, drawn to methods of treating a disorder related to an immune response in an animal comprising administering a known substance that enhances the CD26 signaling pathway. Moreover, the methods are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

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(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.



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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Furthermore, should applicants elect to prosecute groups VIII-XIV or group XV, these group is subject to further restriction as follows. Claims 16, 17, 23-25 are subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 – PRACTICE RE MARKUSH-TYPE CLAIMS – if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 300 (CCPA 1980); and *In re Haas*,

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580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structure feature disclosed as being essential to that utility.

Claims 16 and 25 specifically claim siRNA targeted to caveolin-1 or Tollip. Each target sequence is considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct. Furthermore, a search of more than one (1) of the target sequences claimed in claims 16 and 25 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed target sequences. In view of the foregoing, one (1) target sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect a total of one (1) target sequence from claims 16 and 24. Note that this is not a species election.

Claims 17, 23 and 25 specifically claim nucleotide sequences having SEQ ID Nos. 6, 7, 9, or 10. Each sequence is considered to be unrelated, since each sequence claimed is structurally and functionally independent and distinct. Furthermore, a search of more than one (1) of the nucleotide sequences claimed in claims 17, 23 and 25 presents an undue burden on the Patent and Trademark Office due to the complex

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nature of the search and corresponding examination of more than one (1) of the claimed nucleotide sequences. In view of the foregoing, one (1) nucleotide sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect a total of one (1) nucleotide sequence from claims 17, 23 and 25. Note that this is not a species election.

Claim 1 link(s) inventions of group I-VII. Claim 13 and 26 links inventions of group VIII-XIV. Claim 27 links inventions of group XVI-XXII. Claims 32 and 35 links inventions of groups XXIII-XXIV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), 1, 13, 26, 26, 32 and 35. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file

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folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/  
Examiner AU1635